No. 85-619

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS INC.,
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND DONNA LYNN THOMPSON AS NEXT FRIENDS AND GUARDIANS OF JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRISTOPHER THOMPSON, INDIVIDUALLY AND DONNA LYNN THOMPSON, INDIVIDUALLY, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF OF PETITIONER

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Petition for Certiorari filed October 11, 1985
Certiorari Granted December 2, 1985

QUESTIONS PRESENTED

1. Where a plaintiff alleges that a violation of a specific federal regulatory statute constitutes a rebuttable presumption of negligence and that such violation directly and proximately caused injury to plaintiff, does such claim "necessarily depend" on resolution of an issue of federal law, so as to vest subject matter jurisdiction in the district court?

2. Where a claim which "necessarily depends" on resolution of an issue of federal law is joined with other claims not based on federal law, which would, if plaintiff prevails, obviate the federal question, does the pendency of such local claims deprive the district court of jurisdiction?

LIST OF PARTIES

The caption of the case in this Court does not reflect that there are two cases involved in this matter. The cases were decided together by the District Court and were consolidated by the Court of Appeals. The names of the Respondents in the second case are Neil Frazer MacTavish and Margaret MacTavish as next friends and guardians of Neil MacTavish, Neil Frazer MacTavish, individually, and Margaret MacTavish, individually.

Petitioner is a subsidiary of The Dow Chemical Company. The following subsidiaries and affiliates of The Dow Chemical Company have outstanding securities in the hands of the public: Dow Banking Corporation; Dow Chemical Iberica S.A.; Gruppo Lepetit S.p.A.; Ivon Watkins-Dow Limited; Laboratorios Industriales Farmaceuticos Ecuatorianos; Merrell Toraude et Compagnie; Oronzio De Nora Impianti Elettrochimici S.A.; and Pacific Chemicals Berhad.

TABLE OF CONTENTS

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OPINIONS AND JUDGMENTS BELOW

The opinion of the Court of Appeals is reported at 766 F.2d 1005 (6th Cir. 1985) and is printed in the Joint Appendix ("J.A.") at 8-10. The judgment of the Court of Appeals is printed at J.A. 6-7. The opinion of the District Court is unreported and is printed at J.A. 13-16. The judgments of the district court are printed at J.A. 11-12.

JURISDICTION

The judgment of the United States Court of Appeals for the Sixth Circuit was entered and filed on July 15, 1985. J.A. 6-7. The 90th day after such judgment was Sunday, October 13, 1985. The petition for a writ of certiorari was filed October 11, 1985, and was timely under 28 U.S.C. § 2101(c). The petition for a writ of *certiorari* was granted by an Order filed December 2, 1985. This Court has jurisdiction to review the judgment of the Court of Appeals by writ of *certiorari* under 28 U.S.C. §§ 1254(1), 2101(c).

STATUTORY PROVISIONS INVOLVED

This case involves allegations of violations of certain sections of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. § 301, *et seq.*, which are contained in Respondents' complaints printed at J.A. 17-26, 27-35, and are set forth verbatim in the Appendix to the Petition for a Writ of Certiorari at 10a-11a, or set forth in the body of this brief.

STATEMENT OF THE CASE

The Parties

Petitioner Merrell Dow Pharmaceuticals Inc. (formerly known as Richardson-Merrell, Inc.) is a Delaware Corporation with its principal place of business in Hamilton County, Ohio. The Respondents are Larry James Christopher Thompson and Donna Lynn Thompson, Canadian citizens residing in Napanee, Ontario, and Neil Frazer MacTavish and Margaret MacTavish, British subjects residing in LinLithgow, Scotland. On September 1, 1983, the Thompsons and MacTavishs brought separate suits against the Petitioner in the Court of Common Pleas, Hamilton County, Ohio, at Cincinnati. They sued both individually and as next friends of their minor children, Jessica Thompson and Neil MacTavish.

The Complaints

The Respondents are represented by the same counsel. Their complaints are identical in legal theory and structure and nearly identical in language. Respondents allege that their minor children were born with birth defects as a result of their mothers' ingestion, during pregnancy, of Bendectin, a prescription drug made and marketed in the United States by Petitioner.[1]

Each complaint consists of six numbered "causes of action." The first three respectively allege negligence, breach of express and implied warranties and strict liability in tort. The Sixth Cause of Action alleges gross negligence and asserts a claim for punitive damages. The Fourth and Fifth Causes of Action, however, are not so easily categorized.

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[1] In moving for remand to state court, Respondents admitted that they did not claim to have taken Bendectin made in the United States by Petitioner, but Debendox, a similar drug made in the United Kingdom and sold by a subsidiary of Petitioner in that nation. Petitioner did not make or sell Debendox, nor did it make or sell Canadian "Bendectin," the only similar drug available to Mrs. Thompson in Ontario. Respondents' undisclosed (and factually inaccurate) equation of American Bendectin with Debendox and the Canadian drug is a consistent feature of their complaints.

The Fourth Cause of Action quotes, cites to or paraphrases numerous provisions of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, 21 U.S.C. § 301, *et seq.* The last three paragraphs of the Fourth Cause of Action state:

> 25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 301 of 52 Stat 1040.
>
> 26. *That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant* herein enumerated, constitutes a rebuttable presumption of negligence.
>
> 27. *That the Defendant's violation of said Federal Statutes directly and proximately caused* the injuries suffered by said Minor. . . .

J.A. 22-23, 32 (emphasis added).

The Fifth Cause of Action alleges, *inter alia*,

> 31. *The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food & Drug Administration, as required by law.*
>
> 32. *That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused* the injuries suffered by said Minor. . . .

J.A. 23-24, 33 (emphasis added).

Proceedings In The District Court

Petitioner filed timely petitions for removal from the Common Pleas Court to the U.S. District Court for the Southern District of Ohio, Western Division. Those petitions alleged, as a ground for removal, that Respondents' Fourth Cause of Action was "an alleged claim arising under the laws of the United States. . . ." J.A. 37, 39-40. Respondents thereafter filed a joint motion to remand these cases to the state court for want of federal jurisdiction. J.A. 42-48. In support of this motion, Respondents stated, in part:

> Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.
>
> This principle of law regarding negligence *per se* has long been adopted by the courts in Ohio, and is indeed the majority rule [Citations omitted].
>
> * * *
>
> In summary, plaintiffs' claim that Merrell's violations of the federal Food, Drug and Cosmetic Act constitute negligence *per se* does not give rise to federal question jurisdiction under 28 U.S.C. § 1331.

J.A. 46-47.

Respondents' motion to remand additionally stated:

> Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of the ingestion of Debendox during pregnancy. Debendox is the British trade name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell. Plaintiffs allege, *inter alia*, that defendant Merrell violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-*et seq.* (52 Stat. 1040-et seq.) [Footnote omitted.]
>
> In their Fourth Cause of Action, plaintiffs allege that defendant violated 21 U.S.C. § 352 when it sold Debendox (a/k/a Bendectin) in a branded [sic] and defective

condition. Plaintiffs allege in paragraph 26 of their complaints that Merrell's violation of the Food, Drug and Cosmetic Act in promoting of Debendox constituted a rebuttable presumption of negligence. [Footnote omitted.]

J.A. 43-44.

"Debendox" was a familiar name to both courts below, though it had not been mentioned in either of Respondents' complaints. Like Bendectin of American make, Debendox is a drug indicated for "morning sickness." Its formulation has varied over time and has not always been the same as that of the American drug.[2] One year before the filing of Respondents' complaints, the District Court had dismissed, on grounds of *forum non conveniens*, twelve suits brought by British subjects against the Petitioner alleging that Debendox had caused their children's birth defects. *In Re Richardson-Merrell Inc.*, 545 F. Supp. 1130 (S.D. Ohio 1982), *aff'd sub nom. Dowling* v. *Richardson-Merrell Inc.*, 727 F.2d 608 (6th Cir. 1984). The opinion of the Circuit Court describes the history of Debendox including its manufacture in the United Kingdom (by a corporation unrelated to Petitioner) and its sale and distribution in that nation by a wholly-owned subsidary of the Petitioner, 727 F.2d at 611, *though not by Petitioner, itself.*[3]

The British plaintiffs in *Dowling* v. *Richardson-Merrell Inc.*, (who were represented on appeal by Respondents' counsel) had taken an approach to their pleadings different from the Respondents. The *Dowling* plaintiffs originally filed their suits in federal court based upon diversity of citizenship. Unlike Respondents, they had made no pretense of having

[2] As is apparent from an examination of the *Thompson* complaint, J.A. 17-25, the Thompsons are Canadian rather than United Kingdom citizens. A third drug, of Canadian manufacture, was sold in Canada and bore the name, "Bendectin", though it also varied in formulation from the American drug made by Petitioner.

[3] During the era of Mrs. Thompson's claimed ingestion of the drug, Canadian Bendectin was made and sold in Canada by Petitioner's subsidiary, though not by Petitioner itself.

taken an American made drug. They did not allege or rely upon a violation of the Food, Drug and Cosmetic Act.

Respondents' complaints were filed one year after the District Court had dismissed the *Dowling* suits on grounds of *forum non conveniens*. J.A. 17, 27. Respondents did not then allege that they had taken Debendox, but directly asserted that their obstetricians had prescribed and that they had taken Bendectin and that such was a drug made in the United States by the Petitioner. J.A. 18, 28. Debendox was not mentioned in either complaint.

Petitioner opposed remand on the same grounds asserted herein. While Respondents' motion to remand was pending, Petitioner moved to dismiss both suits on grounds of *forum non conveniens*, relying upon the above-described precedents. In support of its motions to dismiss, Petitioner relied upon affidavits it had filed in a motion to dismiss an Ontario, Canadian-plaintiff action, *Vandervliet* v. *Merrell Dow Pharmaceuticals Inc.*, S.D. Ohio, Case No. C-1-82-470 (Affidavit of William A. Robertson) and *Alexander* v. *Richardson-Merrell Inc.*, S.D. Ohio, Case No. C-1-82-285. (Affidavit of Thomas Ronald Irwin, Supplemental Record, Defendant's Appendix To The Pending *Forum Non Conveniens* Motion. Exhibit 5.) *Alexander* was one of the *Dowling* cases. *Vandervliet* alleged a birth defect resulting from use of Canadian Bendectin. This procedure of incorporation by reference was specifically ordered by the District Court in the "Bendectin" cases in order to reduce the volume of redundant filings in cases presenting identical issues. The affidavits offered in this manner showed the British and Canadian origin of Debendox and Canadian Bendectin and their manufacture and sale by companies other than Petitioner during the pregnancies of Mrs. Thompson and Mrs. MacTavish.

In a single opinion, the District Court denied the Respondents' Motion to Remand and granted the Petitioner's motions to dismiss on grounds of *forum non conveniens*. J.A. 13-16. Addressing the jurisdictional question, the District Court stated:

> Applying the rule as stated in *Smith* [*Smith* v. *Kansas City Title & Trust Co.*, 255 U.S. 180 (1921)], the Court concludes that federal-question jurisdiction exists over these cases and that they were properly removed. Although plaintiffs' fourth cause of action is technically a claim for negligence pursuant to state law, the sole basis for the claim is the alleged violation of the federal Act by defendant. Therefore, the key issue with respect to that cause of action is whether defendant's conduct violated the Act. Phrased in terms of the *Smith* standard, plaintiffs' "right to relief depends upon the . . . application of the . . . laws of the United States."

J.A. 15-16.

The Appeal

Respondents appealed, devoting the entirety of their briefs on appeal to the jurisdictional issue.[4] The Court of Appeals reversed the decision of the District Court on jurisdictional grounds and remanded the Respondents' cases to the District Court with instructions to remand the same to state court. The Court of Appeals stated:

> [A] case removed to federal court under the guise of federal question jurisdiction presents a federal question when it "arises under" federal law. In *Franchise Tax Board*, [*Franchise Tax Board* v. *Construction Laborers' Vacation Trust*, 463 U.S. 1 (1983)] the Court stated:
>
> > Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.
>
> *Id.* at 2856. [463 U.S. at 27-28].

[4] Because respondents did not argue the issue of *forum non conveniens* in the Sixth Circuit, such issue is not before this Court. *City of Eastlake* v. *Forest City Enterprise, Inc.*, 426 U.S. 668, 671 n.2 (1976).

The parties agree that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief *depended necessarily* on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. *See Zeig* v. *Shearson/American Express, Inc.*, 592 F.Supp. 612, 613-14 (E.D. Va. 1984); *State of Florida ex rel. Broward County*, 329 F.Supp. 364, 366, n. 3 (S.D.Fla. 1971).

J.A. 9-10 (emphasis in original). This Court thereafter granted Petitioner's timely petition for a writ of *certiorari*.

SUMMARY OF ARGUMENT

Respondents' complaints accuse Petitioner of causing their childrens' birth defects by "misbranding" Bendectin, Petitioner's American-made drug. Respondents allege that this violation of the Federal Food, Drug and Cosmetic Act was the proximate cause of the birth defects. In fact, and as revealed by Respondents in seeking remand, they attribute their childrens' birth defects to two foreign drugs not of Petitioner's manufacture. Their actual contention is that these foreign drugs were "misbranded" in violation of the Federal Food, Drug and Cosmetic Act. Respondents' Fourth Causes of Action are necessarily dependent on their proof of the federal violations which they allege. This essential federal element of their Fourth Causes of Action renders each suit one "arising under" federal law. In accordance with the principles articulated in *Franchise Tax Board* v. *Construction Laborers' Vacation Trust*, 463 U.S. 1 (1983), Respondents'

cases are within the original jurisdiction of the District Court under 28 U.S.C. § 1331, and their removal, pursuant to 28 U.S.C. § 1441(b), was proper.

Respondents' Fourth Causes of Action allege statutory violations different in character from those typically relied upon for a claim of negligence. Most claims of this type allege violations of simply worded statutes which do not require construction or interpretation. Such concise statutory requirements have sometimes prompted judicial decisions that claims of negligence based on their violation posed only factual questions, but no legal controversy requiring construction of federal law. In contrast, Respondents' complaints show that construction and interpretation of federal law will be required.

Because Respondents accuse Petitioner of "misbranding" the drugs they took by issuing misleading promotional literature on the drug, proof of their claims would require a demonstration that Petitioner's promotional literature did not comply with the Food, Drug and Cosmetic Act and with applicable federal regulations governing advertising of prescription drugs. They invoke a complex regulatory statute rather than a simply worded statute of obvious meaning. On their face, Respondents' complaints show that construction and interpretation of the federal statute will be necessary. This is only more obvious in light of Respondents' admission that they actually attribute their childrens' birth defects to foreign-made drugs rather than to American-made Bendectin. Respondents' inaccurate characterization of their own claims obscures an essential premise of those claims, i.e., that Petitioner could be responsible for the "misbranding" of drugs made and sold in foreign countries by concerns other than itself. This novel federal proposition, on which their Fourth Causes of Action depend, even more clearly presents a federal question conferring jurisdiction over their claims.

While Respondents' negligence claims are not federally created, they do necessitate the construction and interpretation of federal law, as noted above. This Court has previously

declared federal jurisdiction unavailable over negligence claims premised on federal statutory violations. However, these cases concerned the Safety Appliance Act which, by this Court's prior decisions, is to be applied without construction or interpretationwhich might dilute its clear and literal requirements. Furthermore, this Court in *Franchise Tax Board* discarded the premise of these earlier decisions, that only a federally created claim could arise under federal law. The view that a state-created claim can, in no event, arise under federal law was rejected in *Franchise Tax Board*.

The Court of Appeals, in holding that federal jurisdiction was lacking, did not contradict or analyze the District Court's conclusion that Respondents' Fourth Causes of Action were necessarily dependent on the alleged violations of the Food, Drug and Cosmetic Act. Rather, it denied jurisdiction because Respondents had the potential for recovery under their nonfederal claims of negligence, as set forth in their First Causes of Action, and that, accordingly, their "right to relief" did not "necessarily depend" on resolution of the federal question. The Court of Appeals erred in analyzing Respondents' causes of action collectively rather than individually.

It is sufficient to create federal jurisdiction that one claim in Respondents' suits necessarily depends on a substantial question of federal law. It is of no consequence that other claims on which Respondents might recover are not so dependent. The established principle of pendent jurisdiction is that claims arising under federal law should be tried in the same action as those nonfederal claims which arise out of the same occurrences. The potential that a plaintiff will achieve the relief which he seeks based solely on nonfederal grounds cannot deprive the court of jurisdiction over claims which do arise under federal law.

ARGUMENT

I. WHERE A PLAINTIFF ALLEGES THAT A VIOLATION OF A SPECIFIC FEDERAL REGULATORY STATUTE CONSTITUTES A REBUTTABLE PRESUMPTION OF NEGLIGENCE AND THAT SUCH VIOLATION HAS DIRECTLY AND PROXIMATELY CAUSED PLAINTIFF'S INJURIES, SUCH CLAIM "NECESSARILY DEPENDS" ON RESOLUTION OF A SUBSTANTIAL ISSUE OF FEDERAL LAW, SO AS TO VEST SUBJECT MATTER JURISDICTION IN THE DISTRICT COURT.

A. The District Court correctly ruled that the Respondents' Fourth Cause of Action, which alleged Petitioner's liability by reason of its violation, through "misbranding" of Bendectin, of the Food, Drug and Cosmetic Act was a claim necessarily dependent on a substantial issue of federal law and was, therefore, one "arising under" federal law in accordance with 28 U.S.C. § 1331.

In finding that it had jurisdiction over the Respondents' claims, the District Court recognized that the Respondents could not recover on their Fourth Causes of Action without demonstrating that the Petitioner had violated the Food, Drug and Cosmetic Act. Ruling that this necessary federal element was sufficient to sustain subject matter jurisdiction under 28 U.S.C. § 1331, the District Court expressly relied upon the decision of this Court in *Franchise Tax Board* v. *Construction Laborers Vacation Trust*, 463 U.S. 1 (1983). In *Franchise Tax Board*, this Court considered a suit removed from state court to determine whether the case was one "arising under" the laws of the United States. This Court summarized the rule of law governing "federal question" jurisdiction by the following words:

> Under our interpretations, Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action *or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law*.

Id. at 27-28 (emphasis added).

In *Franchise Tax Board*, this Court also paraphrased the alternate ground for federal jurisdiction under 28 U.S.C. § 1331 in several ways:

> We have often held that a case "arose under" federal law *where the vindication of a right under state law necessarily turned on some construction of federal law*, see, *e.g.*, *Smith* v. *Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *Hopkins* v. *Walker*, 244 U.S. 486 (1917). . . . Leading commentators have suggested that for purposes of § 1331 an action "arises under" federal law "*if in order for the plaintiff to secure the relief sought he will be obliged to establish both the correctness and the applicability to his case of a proposition of federal law.*" . . . "[A] case may 'arise under' a law of the United States if the complaint discloses a need for determining the meaning or application of such a law."
>
> * * *
>
> [A] right or immunity created by the Constitution or laws of the United States *must be an element, and an essential one, of the plaintiff's cause of action.*" *Gully* v. *First National Bank in Meridian*, 299 U.S. 109, 112 (1936).
>
> * * *
>
> As an initial proposition, then, the "law that creates the cause of action" is state law, and original federal jurisdiction is unavailable *unless it appears that some*

> *substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims*, or that one or the other claim is "really" one of federal law.
>
> Even though state law creates appellant's causes of action, its case might still "arise under" the laws of the United States *if a well-pleaded complaint established that its right to relief under state law requires resolution of a substantial question of federal law in dispute between the parties.*

Id. at 9, 10, 11, 13 (emphasis added).

The Respondents' Fourth Causes of Action, as pled, were centered solely on their allegation that the Petitioner had violated the Food, Drug and Cosmetic Act by "misbranding" Bendectin. In order to secure the relief sought in the Fourth Cause of Action, Respondents would be obliged to show "the correctness and the applicability" to their case of their proposition that Petitioner "misbranded" Bendectin in violation of the Food, Drug and Cosmetic Act. Such proposition is "an element, and an essential one" of their cause of action. Furthermore, their "rights" asserted in the Fourth Cause of Action will necessarily turn on the Court's construction of the Food, Drug and Cosmetic Act.

B. The court which tries the Respondents' Fourth Cause of Action will be required to construe and interpret the Food, Drug and Cosmetic Act.

The Respondents, in their First Causes of Action (which are incorporated by reference in their Fourth Causes of Action) specifically allege that the plaintiff mothers experienced nausea during pregnancy for which their obstetricians prescribed Bendectin. J.A. 18, 28. They also allege that Bendectin is a prescription drug made and distributed by the Petitioner. *Id.*

Though Respondents do not specifically cite to it, the section of the Act which actually prohibits "misbranding" is 21 U.S.C. § 331 (52 Stat. 1042), as amended. Section 331 states, in pertinent part:

> The following acts and the causing thereof are prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, devise, or cosmetic that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
>
> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

Respondents do not cite to any of the above-quoted provisions, nor do they allege which of them the Petitioner violated. They do not allege that the drugs which they took had moved in interstate commerce or had been delivered for introduction into interstate commerce. However, to show that the drugs that they supposedly took were "misbranded," Respondents would seemingly be obliged to prove as much.

Respondents rather rely upon those sections of the Act which define misbranding. They cite to the following provision of 21 U.S.C. § 352 (52 Stat. 1050, § 502A.)

> § 352. MISBRANDED DRUGS AND DEVICES.
>
> A drug or device shall be deemed to be misbranded —
>
> (a) If its labeling is false or misleading in any particular
>
> * * *
>
> (f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or

against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

* * *

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

Respondents also cite and partially quote, in their Fourth Causes of Action, to section 201 of the Act, 21 U.S.C. § 321, 52 Stat. 1041, § 201, which, in its current form, reads:

(n) If an article is alleged to be misbranded because the labeling *or advertising* is misleading, then in determining whether the labeling *or advertising* is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling *or advertising* fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling *or advertising* relates under the conditions of use prescribed in the labeling *or advertising* thereof or under such conditions of use as are customary or usual.

(Emphasis added.)

In Paragraph 20 of their respective Fourth Causes of Action, Respondents quote to an outdated version of this statutory provision which did not include the words "or advertising". Nonetheless, the Respondents' allegation of "misbranding" in Paragraph 20 is expressly premised on "the *promotion* of said drug, Bendectin, by the defendant . . . without revealing or attempting to reveal any facts, material to consequences which may result to the unborn offspring of mothers receiving the drug. . . ." J.A. 22, 32 (emphasis added).

What the Respondents mean by the "promotion of said

drug" is not specified in their Fourth Causes of Action. However, in Paragraph 29 of their Fifth Causes of Action, they allege Petitioner's "false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side-effects of its product Bendectin . . . made in promotional literature, product inserts and by detailmen to prescribing physicians." J.A. 23, 33.

Since the Respondents do not allege that they received any label (misleading or not) prepared by the Petitioner, nor any product insert (such inserts often do not accompany drugs dispensed by prescription) it is presumably based on the promotional efforts of the Petitioner that Respondents deem the drugs they took "misbranded."

Only one section of 21 U.S.C. § 352 may render a drug "misbranded" based upon advertisements and promotional literature. 21 U.S.C. § 352(n) provides, in pertinent part, that a drug is "misbranded":

In the case of any prescription drug *distributed or offered for sale in any State*, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of . . . (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title . . . .

(Emphasis added.)

Under this section, Respondents would be obliged to show that the information included in any advertisements by Petitioner failed to comply with regulations issued by the Secretary in accordance with section 352(n). To judge the compliance of the advertisements regarding Bendectin with applicable regulations requires construction and interpretation of those regulations.

Furthermore, section 503 of the Act, 21 U.S.C. § 353, exempts many prescription drugs from a number of the branding requirements of section 352. Such provisions, in pertinent part, state:

> (b)(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a), (i)(2) and (3), (k), and (l) of said section, and the packaging requirements of subsections (g), (h), and (p) of said section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

By reason of this provision, a pharmacist who fills a prescription and includes the usual data appearing on the prescription labels commonly issued in this country thereby sells a drug which is, by definition, *not* misbranded, at least in terms of advertising.

Mrs. Thompson and Mrs. MacTavish each allege that they took Bendectin pursuant to the prescription of a physician. J.A. 18, 28. Assuming that the pharmacist or chemist who filled the prescription did so by means of the procedure universally followed in the United States, and assuming that the Respondents' obstetricians were duly licensed to prescribe drugs, many subsections of section 352 of the Act become unavailable to the Respondents to support their allegation of misbranding. Among these are subsections (f)(2) and (j) upon which they expressly rely and subsection (n), the only provision defining false advertising as "misbranding."

Respondents' claim that Bendectin was "misbranded" through misleading promotion of that drug is a far cry from the typical claim that a statutory violation constitutes negligence. Such claims ordinarily rely on statutes which are concise and self-explanatory. The meaning of such statutes does not depend on an understanding of the governmental policies underlying their enactment. The defendant is normally accused of a discrete act or omission which would violate a clear and concrete prohibition. In contrast, Respondents' accusation requires an evaluation of the entire promotional program employed by Petitioner and a weighing of that program against the statute's objectives and those of the regulations implementing it. By its nature, Respondents' accusation presents a mixed question of law and fact, requiring judicial interpretation of the statute and regulations.

These issues of statutory construction and interpretation were never considered below because of the dismissal of Respondents' cases for *forum non conveniens*. However, when the Respondents decided to accuse Petitioner of misbranding prescription drugs by issuing misleading promotional information, they pled a cause of action which will require such consideration, whether in federal court or elsewhere. They thus embraced legal propositions that do not rely upon settled law, but raise new implications concerning the scope of a complex regulatory statute. A federal court should decide these issues.

Respondents' complaints, on their face, promise a need for construction and interpretation of the Food, Drug and Cosmetic Act. The fact that they actually attribute their childrens' birth defects to Debendox, of British make, and Canadian Bendectin will also compel a decision as to whether the Act applies beyond this nation's borders. The court which tries Respondents' suits will be obliged to consider several issues of the extraterritorial significance of the Food, Drug and Cosmetic Act. Among those are the following:

1. Whether the activities of a foreign corporation

(regulated in its activities by the law of its homeland) in manufacturing, labeling and selling a drug outside the United States are, in any respect, subject to the Food, Drug and Cosmetic Act.

2. Whether an American corporation may be guilty of "misbranding" a drug made, marketed, sold and ingested in a foreign country by reason of its parent-subsidiary relationship with the foreign seller or by reason of its development, manufacture, sale and testing of a similar, predecessor drug in the United States.

3. Whether drugs which have not moved in "interstate commerce" within the terms of the Food, Drug and Cosmetic Act may nonetheless be deemed "misbranded" by reason of alleged "misbranding" of a similar predecessor drug in the United States.

It was not only Bendectin but also Debendox which Petitioner is accused of "misbranding". J.A. 43-44. The Act on its face defines as "misbranding" the issuance of misleading promotional materials, but only as to prescription drugs "distributed or offered for sale in any state". 21 U.S.C. § 321(a)(1). May the allegation that Bendectin, made and distributed in the U.S., was "misbranded," render the drugs supposedly taken by the Respondents in Canada and Scotland "misbranded" within the term of the Act? Whatever the answer, it is assuredly an interpretative question of federal law and not a fact question for the jury. The need for construction and interpretation of the Food, Drug and Cosmetic Act is clear.

Respondents' complaints, however, erroneously report ingestion of American-made Bendectin, an error admitted in seeking remand. Does the "well-pleaded complaint" rule prohibit a federal court's taking notice of the actual legal contentions of a plaintiff if the complaint obscures those contentions by factual error? In *Franchise Tax Board*, this Court stated:

> Although we have often repeated that "the party who brings a suit is master to decide what law he will rely upon," *The Fair* v. *Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913), *it is an independent corollary of the well-pleaded complaint rule that a plaintiff may not defeat removal by omitting to plead necessary federal questions in a complaint*, see *Avco Corp.* v. *Aero Lodge No. 735, Int'l Assn. of Machinists*, 376 F. 2d 337, 339-340 (CA 6 1967), aff'd, 390 U.S. 557 (1968).

463 U.S. at 22 (emphasis added). The "well-pleaded complaint" rule permits a plaintiff to avoid removal by declining to rely on federal law for his claim, *only if such reliance is not necessary and unavoidable by the nature of the claim*. Here, Respondents' reliance on federal law is clear, but the novelty of their claim for extraterritorial application of the Food, Drug and Cosmetic Act is veiled by inaccurate statements as to the name and origin of the drugs which they claim to have taken.

The 'well-pleaded complaint' rule permits a plaintiff to block federal jurisdiction by choosing not to rely on federal law. It ought not allow a similar obstruction through erroneous factual allegations. The jurisdiction of the District Court in the instant cases should be judged by the contentions revealed by Respondents in urging remand, rather than by the inaccurate allegations of their complaints. A case may become removable after a complaint is filed. 28 U.S.C. § 1446(b). It will not offend the well-pleaded complaint rule to deem the Respondents' complaints "amended" to allege the "true" allegations of their claims as of their first revelation of those allegations in their motion to remand.

Whatever view this Court may take as to whether it is bound to consider only the allegations of the complaints, such will not control the jurisdictional decision. Trial of the claimed violations of the Food, Drug and Cosmetic Act, even as applied solely to American Bendectin, will require construction and interpretation of the statute. That necessity

merely becomes more obvious when the drugs allegedly taken are properly identified as products made and sold in the foreign countries of the Respondents' residence.

C. The federal question whether the Petitioner was guilty of "misbranding" a drug under the Food, Drug And Cosmetic Act is "substantial."

In their complaints, Respondents allege that their children's birth defects were caused by Bendectin which had been "misbranded" by the Petitioner in violation of the Food, Drug and Cosmetic Act. In their motion to remand, they reveal their actual contention that the Petitioner is responsible for the "misbranding" of *Debendox* in violation of the same Act. Under either proposition, the federal question upon which the Respondents' Fourth Cause of Action necessarily depends is a substantial one involving unsettled law.

The Petitioner, of course, denies that it misbranded the drug which it manufactured, i.e., American-made Bendectin or that the drugs available to the Respondents (Debendox and Canadian-made Bendectin) were misbranded. Further, the Petitioner denies the legal premise implicit in the Respondents' Fourth Cause of Action, i.e., that it may be accused of misbranding drugs produced in other countries by companies other than itself. Petitioner, indeed, maintains that the alleged "misbranding" of Debendox or Canadian Bendectin is a matter totally beyond the scope of the Food, Drug and Cosmetic Act and is governed entirely by the laws of Canada and of the United Kingdom. J.A. 50. However, Respondents have not invoked Canadian or British law, but that of the United States.

The questions Respondents' claims pose are "substantial" in the sense which this Court has applied as a jurisdictional test. In *Hagans* v. *Lavine*, 415 U.S. 528, 536-37 (1974) (citing *Ex parte Poresky*, 290 U.S. 30, 31-32 (1933)), this Court stated that, to be insubstantial, a federal claim must be "obviously without merit" or clearly foreclosed by prior Supreme Court

precedent, "leaving no room for the inference that the questions sought to be raised can be the subject of controversy." In *Mt. Healthy City Board of Education* v. *Doyle*, 429 U.S. 273, 279 (1976), this Court noted:

> [W]here an action is brought under § 1331, . . . jurisdiction is sufficiently established by allegation of a claim under the Constitution or federal statutes, unless it 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction. . . .' *Bell* v. *Hood*, 327 U.S. 678, 682 (1946); *Montana-Dakota Utilities Co.* v. *Northwestern Pub. Serv. Co.*, 341 U.S. 246, 249 (1951).

Quite obviously, the allegations of the Respondents' Fourth Cause of Action were not "made solely for the purpose of obtaining jurisdiction" but with an earnest purpose to the contrary. While Petitioner regards the Respondents' federal contentions as improbable, the Respondents obviously do not agree. They wish to press their claim that Petitioner may be held liable for "misbranding" and wish to do so in state court rather than federal court. Should this Court conclude that the district court lacked jurisdiction, the federal controversies raised by the Respondents' complaints will be decided in state courts.[5] Such issues are not frivolous on their face and, accordingly, they have sufficient substance to sustain the district court's conclusion that federal jurisdiction is present.

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[5] Some courts have noted that, in addition to the alleged federal law violations being an essential element of the plaintiffs' state law cause of action, an action can arise under the laws of the United States if "a distinctive federal policy of a federal statute requires application of federal legal principles for its disposition." *Hages* v. *Aliquippa & Southern R.R. Co.*, 427 F. Supp. 889, 893 (W.D. Pa. 1977). *See also North Davis Bank* v. *First National Bank of Layton*, 457 F.2d 820, 823 (10th Cir. 1972); *Miller* v. *Standard Federal Savings & Loan Assn.*, 347 F. Supp. 185, 187 (E.D. Mich. 1972). This theory of the propriety of federal jurisdiction is particularly appropriate in the present actions because of the comprehensive nature of regulation of the pharmaceutical industry through the Federal Food, Drug and Cosmetic Act.

In *State of New York by Abrams* v. *Citibank, N.A.*, 537 F. Supp. 1192 (S.D.N.Y. 1982), the Court stated:

D. Where this Court and lower federal courts have rejected federal jurisdiction over claims of negligence based on federal violations, such decisions have not applied or considered the alternative basis for federal question jurisdiction recognized in *Franchise Tax Board.*

In the courts below, the Respondents relied upon certain precedents for the proposition that a claim of negligence based upon a violation of federal law is not a basis for federal jurisdiction. In fact, and as the District Court found, the cases relied upon by the Respondents are inapposite. Such cases either (1) rely upon the now-rejected view that only a federally created cause of action can sustain federal question jurisdiction, (2) were based upon the settled meaning of the federal statutes there in issue, or (3) were unwarranted extensions of earlier precedents.

1. In *Franchise Tax Board,* this Court acknowledged that a claim need not be federally created in order to "arise under" federal law.

In *Franchise Tax Board*, this Court recalled Justice Holmes' definition of "arising under" jurisdiction:

> The most familiar definition of the statutory "arising under" limitation is Justice Holmes' statement, "A suit arises under the law that creates the cause of action."

Federal jurisdiction in this case is particularly appropriate, since EFTA will be construed here for the first time. No reported decision construing the statute has been found. While federal courts should assume that state courts are competent to decide federal as well as state-law questions, Congress has in its jurisdictional statutes made the federal courts an available and preferred forum for federal law issues, when a plaintiff's claim depends upon their resolution. *See England* v. *Medical Examiners*, 375 U.S. 411, 415, 84 S. Ct. 461, 464, 11 L.ED.2d 440 (1964). That policy has special force where . . . the only forum for federal corrective action in the event of erroneous decisions would be the Supreme Court of the United States, on discretionary review.

Id. at 1197-98.

> *American Well Works Co.* v. *Layne & Bowler Co.*, 241 U.S. 257, 260 (1916). However, it is well settled that Justice Holmes' test is more useful for describing the vast majority of cases that come within the district court's original jurisdiction than it is for describing which cases are beyond district court jurisdiction. We have often held that a case "arose under" federal law where the vindication of a right under state law necessarily turned on some construction of federal law, see, *e.g.*, *Smith* v. *Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *Hopkins* v. *Walker*, 244 U.S. 486 (1917), and even the most ardent proponent of the Holmes test has admitted that it has been rejected as an exclusionary principle
> . . . .

463 U.S. at 8-9 (citations omitted).

Despite the "well settled" principle that the Holmes "definition" is **not** exclusive, the precedents which have denied federal jurisdiction where negligence claims are founded on asserted violations of federal statutes have often done so on the implicit or explicit premise that the Holmes test *is* an exclusive definition of "arising under" jurisdiction. In *Jacobson* v. *New York, N.H. & H.R. Co.*, 206 F.2d 153 (1st Cir.), *cert. granted*, 346 U.S. 895 (1953) (solely on the question of diversity jurisdiction), *aff'd per curiam*, 347 U.S. 909 (1954), the First Circuit affirmed the district court's dismissal of a claim for wrongful death of a passenger who had been fatally injured in a railroad accident. The plaintiff had alleged negligence based upon a violation of one section of the Safety Applicance Act, i.e., 45 U.S.C. § 1. The First Circuit held that there was no private right of action for passengers under the Safety Appliance Act and that such claim, *for that reason*, did not arise under federal law so as to sustain jurisdiction under 28 U.S.C. § 1331. The Court stated:

> Furthermore, it follows that where there is no diversity of citizenship such an action cannot be maintained in a

federal district court, since the liability for damages and the corresponding private right of action, if any, are created by state law.

206 F.2d at 157 (citations omitted).

The First Circuit in *Jacobson* did not consider whether "the vindication of a right under state law necessarily turned on some construction of federal law . . .," thus to vest federal jurisdiction notwithstanding the fact that the cause of action was created by state law. *Jacobson*, in effect, applied the Holmes test as a principle of exclusion.

It is also true that this Court has, in decisions predating *Franchise Tax Board* (and perhaps also predating the appreciation of the limitations of the Holmes test as a principle of exclusion) at times reached the same result. In *Moore* v. *Chesapeake & Ohio Ry. Co.*, 291 U.S. 205 (1934), this Court considered a claim under the Kentucky Employers Liability Act, a statute which reenacted, with reference to intrastate railroad traffic, the provisions of the Federal Employers Liability Act (FELA).

In *Moore*, this Court *sustained* "jurisdiction" over a state law claim because it did *not* arise under federal law. This reversed a decision of a circuit court which had rejected "jurisdiction" over the same claim because it *had* arisen under federal law. This anomalous result was based on the view at that time that venue statutes were jurisdictional.

Moore claimed to have been injured in attempting to uncouple freight cars. He blamed his injury on a defective uncoupling lever which, he alleged, constituted a violation of the Safety Appliance Act. Pleading alternately, Moore first alleged that his injury had occurred in interstate commerce, basing his first count on the FELA. Secondly, he alleged an injury actionable under the Kentucky Act because incurred in *intrastate* commerce. The Safety Appliance Act, as then constituted, applied to all carriers engaged in interstate commerce, regardless of whether the particular rail cars were at

any particular time engaged in intrastate traffic. Moore apparently cited the alleged violation of the Safety Appliance Act as negligence *per se* under the federal statute and state law. He also urged that such violation precluded the affirmative defenses of contributory negligence and assumption of the risk.

During the era in which Moore sued, the venue statute required suits based, even in part, on "federal question jurisdiction" to be filed only in the judicial district of the defendant's residence. *Chesapeake & Ohio Ry. Co.* v. *Moore*, 64 F.2d 472, 475 (7th Cir. 1933), *rev'd sub. nom.*, *Moore* v. *Chesapeake & Ohio Ry. Co.*, 291 U.S. 205 (1934). Suits based *solely* on diveristy of citizenship could be filed in either defendant's or plaintiff's place of residence. Moore sued in his home state. For his alternative claim, he had alleged both diversity of citizenship and a claim arising under the Federal Safety Applicance Act, as well as under Kentucky law. The Circuit Court took this allegation at face value and ruled: "[J]urisdiction and venue were in the district of appellant's residence, and not in the Northern District of Indiana."[6] 64 F.2d at 476.

This Court reversed the Circuit Court, holding that diversity was the sole basis for federal jurisdiction and ruling that the case had been properly brought in Moore's district of residence. The Court stated:

> The Federal Safety Appliance Acts prescribe duties, and injured employees are entitled to recover for injuries sustained through breach of these duties. [Citation omitted]. Questions arising in actions in state courts to recover for injuries sustained by employees in intrastate commerce and relating to the scope or construction of the Federal Safety Appliance Acts *are, of course, federal questions which may appropriately be reviewed in this Court*. [Citations omitted]. But it does not follow that a suit brought under the state statute which defines liabili-

[6] Venue over Moore's FELA claim was founded on a special venue provision of that Act. 45 U.S.C. § 56.

ty to employees who are injured while engaged in intrastate commerce, and brings within the purview of the statute a breach of the duty imposed by the federal statute, should be regarded as a suit arising under the laws of the United States and cognizable in the federal court in the absence of diversity of citizenship. The Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing actions for enforcing these rights. * * * [T]he Act made no provision as to the place of suit or the time within which it should be brought, or as to the right to recover, or as to those who should be the beneficiaries of recovery, in case of the death of the employee. . . .

* * *

The federal statue in the present case touched the duty of the master at a single point and, save as provided in the statute, the right of the plaintiff to recover was left to be determined by the law of the state.

> We are of the opinion that the second paragraph of the complaint set forth a cause of action under the Kentucky statute and, as to this cause of action, the suit is not to be regarded as one arising under the laws of the United States. . . .

291 U.S. at 214, 215, 216, 217 (quoting *Minneapolis, St. P. & S.S. Ry. Co.* v. *Popplar*, 237 U.S. 369, 372 (1915)).[7]

This Court in *Moore* held that a state-created claim prem-

[7] *Moore* is also noteworthy in that it exemplifies an outmoded view of federal pendant jurisdiction. The plaintiff in *Moore* brought two claims, one directly invoking the Federal Employers Liability Act, a claim as to which the court found a specific grant of federal jurisdiction under that Act, i.e., 45 U.S.C. § 56. The plaintiff had alternatively pled that *the same injury* was incurred in *intrastate* commence, invoking the Kentucky act. Today, the jurisdiction of the court over *Moore's* alternative state claim would be readily found under the principles of pendent jurisdiction. *United Mine Workers* v. *Gibbs*, 383 U.S. 715 (1966).

ised on a federal violation did not "arise under" federal law. The effect of that ruling was to sustain venue, and, hence, jurisdiction over that claim. No party argued as a ground of jurisdiction, that Moore's Kentucky law claim was necessarily dependent on his allegation of a violation of the Safety Appliance Act. This Court did not consider such a basis for jurisdiction.

Moore applied the Holmes test for federal question jurisdiction *as an exclusive test*. All the holding really "excluded" in that case, was the defendant's venue objection. Had this Court in *Moore* considered that jurisdiction might rest on an essential question of federal law included in the Kentucky claim, it would not necessarily have reached the same result. As noted below, the Safety Appliance Act had been often litigated prior to *Moore*, and this Court had expressed the view that the statute was clear and that its provisions permitted no construction or interpretation. It is questionable whether this Court would have found jurisdiction under the alternate ground of jurisdiction discussed in *Franchise Tax Board*.

In its broad rule of law, *Moore* weighs against the Petitioner's position. However, this Court's recent ruling in *Franchise Tax Board* amends the implicit assumption in *Moore* that no state-created claim can "arise under" federal law. The peculiar facts in *Moore*, the settled meaning of the federal statutes there in issue, and *Franchise Tax Board* all compel the conclusion that *Moore* should not control the jurisdictional decision in the instant cases.

In *Crane* v. *Cedar Rapids & Iowa City Ry. Co.*, 395 U.S. 164 (1969), this Court reviewed a decision of the Supreme Court of Iowa on the question of whether the Federal Safety Appliance Act provision withdrawing the defenses of contributory negligence and assumption of the risk was applicable in a state-created claim by a nonemployee of the defendant railroad. The petitioner had sued in state court, alleging injuries resulting from a violation of the Safety Appliance Act through maintenance by the defendant of a

freight car with a defective coupler. On *certiorari*, the petitioner argued that the Iowa trial court had erroneously submitted to the jury the issue of contributory negligence. This Court ruled that state law must control the availability of affirmative defenses under state causes of action.

No party in *Crane* invoked original federal jurisdiction. Neither did this Court directly address whether the alleged federal violation was a "necessary element" of Crane's state claim or under what circumstances such a holding might support federal jurisdiction. Purely as dictum, the Court noted: "In contrast, the nonemployee must look for his remedy to a common law action in tort, which is to say that he must sue in a state court, in the absence of diversity, to implement a state cause of action." 395 U.S. at 166 (citations omitted). This dictum simply does not address the second alternative basis for federal jurisdiction noted in *Franchise Tax Board*. It applied the Holmes test as a principle of exclusion.

E. Lower federal courts have often failed to distinguish state claims which merely pose factual controversies governed by settled federal law from those which will require construction and interpretation of federal statutes.

As *Jacobson* v. *New York, N. H. & H. R. Co.*, 206 F.2d 153 (1st Cir.), *cert granted*, 346 U.S. 895 (1953), *aff'd per curiam*, 347 U.S. 909 (1954), illustrates, the simplicity of the Holmes test for federal question jurisdiction has made it difficult for the lower federal courts to abandon it as an exclusionary rule. Procedurally, orders of the district courts applying the Holmes test and ordering remand of removed cases have evaded review, since such remands by district courts prior to final judgment are not appealable. 28 U.S.C. § 1447(d). However, orders by courts of appeals directing remand to state court are subject to review. *Grubbs* v. *General Electric Credit Corp.*, 405 U.S. 699 (1972). The lower federal courts have widely displayed reluctance to accept a test of

federal question jurisdiction which is broader than Justice Holmes' maxim that "a suit arises under the law that creates the cause of action." They have demonstrated this reluctance in sometimes strained attempts to minimize the federal element of a plaintiff's state-created cause of action.

An often cited (and often misapplied) case on this issue is the decision of the Tenth Circuit in *Andersen* v. *Bingham & G. Ry. Co.*, 169 F.2d 328 (10th Cir. 1948). The plaintiff in *Andersen* sought damages for personal injuries sustained in an auto-train collision. He alleged ten separate grounds of negligence, including a violation of a single provision of the Safety Appliance Act, 45 U.S.C. § 1, in that the defendant operated its train in interstate commerce with defective brakes. The circuit court in *Andersen* first accurately recalled the general test of federal question jurisdiction:

> In order for a suit to be one arising under the laws of the United States within the meaning of the removal statute, it must really and substantially involve *a dispute or controversy in respect of the validity, construction, or effect* of such laws, upon the determination of which the result depends. A right or immunity created by the laws of the United States must be an essential element of the plaintiff's cause of action, and the right or immunity must be such that it will be supported if one construction or effect is given to the laws of the United States and will be defeated if another construction or effect is given. . . .

Id. at 329-30 (emphasis added).

The court then addressed the fact that the plaintiff had invoked a violation of the federal act as a basis for liability:

> The allegations in the complaint charging as an element of negligence failure on the part of the defendant to comply with the exactions of the Safety Appliance Act *merely tendered the issue of fact whether the train was operated without brakes being in operative condition as required by the Act. The complaint did not present any issue or controversy in respect to the validity, construc-*

> *tion, or effect of the Act*. It did not set forth any right or immunity which would be supported if the Act be given one construction or effect and defeated if given another. While the pertinent provisions of the Act lurked in the background as creating a duty the breach of which constituted negligence, the right of action available and the incidents of such right of action sprang from the law of Utah. It did not arise under the laws of the United States.

Id. 330-31 (citations omitted) (emphasis added).

The plaintiff in *Andersen* had sued under 45 U.S.C. § 1, a statute which consists of only 92 words which make it unlawful to operate a train in interstate commerce which is not equipped so that the engineer can control the train's speed without requiring brakemen to use hand brakes. The Tenth Circuit had good cause to assume that Andersen's claim would require no *construction or interpretation* of that federal statute.

This Court had, years before, expressed displeasure with attempts to "interpret" the Safety Appliance Act to permit "equivalent" compliance as a substitute for its clear and literal meaning. *St. Louis Iron Mountain and Southern Ry.* v. *Taylor*, 210 U.S. 281 (1908); *Saint Joseph & Grand Island Ry. Co.* v. *Moore*, 243 U.S. 311 (1917). Accordingly, the precedents against anything but a literal reading of the Act supported the conclusion of the Tenth Circuit in *Anderson* that only fact questions would be presented.[8] The brake statute could be read to the jury verbatim and be readily understood by a juror of ordinary intelligence.[9] For this

[8] It is significant that *Moore*, *Crane* and *Jacobson*, as well as *Andersen* and *Owens* v. *New York Central R.R. Co.*, 267 F.Supp. 252 (E.D.ILL. 1967), discussed below, all concerned the relatively simple provisions of the Safety Appliance Act.

[9] The reference to "interstate commerce" in the statute is the only legal phrase contained therein. There is no indication that the status of the train as being in "interstate commerce" was at issue in *Andersen*.

reason, the court reasonably concluded that no federal *legal* controversy would be presented.

The circuit court in *Andersen* logically distinguished between a federal legal controversy and a factual controversy to which *settled* federal law must be applied. Nonetheless, *Andersen* has often been cited seemingly for the proposition that no allegation of a violation of any federal law poses anything more than a factual question for the jury. This is a much broader rule of law than that propounded by the Tenth Circuit in *Andersen* and one which has been applied to quite dissimilar federal statutes.

In *Boncek* v. *Pennsylvania Ry. Co.*, 105 F. Supp. 700 (D.N.J. 1952), the district court considered a claim by certain individuals for damages resulting from an explosion. The fifth count of the complaint alleged the negligence of defendants in manufacturing, packing, handling and transporting explosives contrary to applicable statutes of the United States, the State of New Jersey and the city of South Amboy, New Jersey. While acknowledging the potential federal element of one claim of negligence, the court noted:

> But no recovery is sought under and by virtue of the terms of any federal statutes or regulations. The right of action for breach of such duty (if we assume that Congress by such statutes and regulations prescribed absolute duties and created correlative rights in favor of injured persons) was created by and enforceable under the laws of the state of New Jersey, and does not really and substantially involve a controversy respecting the validity or construction of a law of the United States upon the determination of which the result depends.

Id. at 706. The court then cited to *Andersen* and to its "issue of fact" conclusion. The federal regulations governing explosives were not even specifically cited or discussed in the opinion. The Court in *Boncek* did not consider whether an adjudication of the plaintiff's fifth count of negligence might

require a *construction or interpretation* of the federal laws governing handling of explosives. The result in *Andersen* was applied, but its rational left behind.

In *Owens v. New York Central R.R. Co.*, 267 F. Supp. 252 (E.D. Ill. 1967), the district court remanded a claim which, in two counts, alleged injury resulting from a violation of the Safety Appliance Act, in particular, 45 U.S.C. § 2. This statute was even simpler in its language than the power brake requirement at issue in *Andersen*. It required automatic couplers on railroad cars. The district court in *Owens* again relied upon *Andersen* for the propositon that *no construction* of the federal statute was required.

The court in *Owens* also relied upon the case of *Dennis* v. *Southeastern Aviation, Inc.*, 176 F. Supp. 542 (E.D. Tenn. 1959). The court in *Dennis* remanded a removed case which had alleged wrongful death in a plane crash resulting from violations of regulations promulgated under the Federal Civil Aeronautics Act. Without discussing the substance of the Civil Aeronautics rules, the *Dennis* court announced:

> *No question appears as to the interpretation of the rules, the only question being one of fact whether they were violated.*
>
> * * *
>
> Bearing in mind that the allegation as to violation of the federal regulation simply tendered another issue of negligence, and involved no question of the validity or interpretation of the regulation, and bearing in mind further that all doubts should be resolved in favor of remand [citations omitted] the court is of the opinion that remand should be granted.

Id. at 543-44 (emphasis added). The district court in *Boncek* did not explain its observation that no need was presented for interpretation of the Civil Aeronautics rules. Perhaps the rules which the complaint put in issue were as simple and noncontroversial as those in *Andersen*. However, this does not

imply that *any* alleged federal violation can be submitted to a jury without the need for an interpretation of the statute by the court.

F. The legal fiction that a negligence claim premised on a federal statutory violation always poses only factual questions should be discarded in those rare cases where the complaint shows the necessity for construction and interpretation of federal law.

The *Andersen* case, which concerned a simple and noncontroversial federal statute which (as this Court had ruled) left no room for construction or interpretation, has been progressively applied to more and more complicated statutes and regulations on the never-reexamined assumption that such federal laws would pose no necessity for construction or interpretation by a federal court, but only fact questions. Over the years, the fundamental premise of *Andersen*, that the railroad brake law (the only statute there in issue) did not require interpretation or construction, has been forgotten. *Andersen* and its progeny have come to stand for the proposition that no allegation of negligence based upon violation of federal law can support federal jurisdiction. This is illustrated in the case of *Zieg* v. *Shearson/American Express Inc.*, 592 F. Supp. 612 (E.D. Va. 1984), a case relied upon by the Sixth Circuit in ordering remand of the Respondents' cases.

In *Zieg*, the plaintiffs alleged negligence of a commodities broker, asserting that violations of the Commodities Exchange Act constituted negligence *per se*. The Virginia district court nodded to this federal aspect of the plaintiffs' claims only in passing, stating: "A state law negligence cause of action that incorporates federal law by reference does not 'arise under' federal law. *See, e.g., Owens* v. *New York Central R. Co.*, 267 F. Supp. 252 (Ill. 1967); 13 Wright Miller & Cooper § 3562 at 411-412 (1975)." 592 F. Supp. at 614. *Owens* had concerned a 59-word federal statute requiring

automatic couplers in simple English. The *Owens* premise, that the federal statute there in issue posed no need for interpretation, was applied, without discussion, to a case alleging violations of the Commodities Exchange Act.

As in *Dennis*, the precise nature of the claimed federal violation is not disclosed in the *Zieg* opinion. However, the Court's assumption that the jury could be instructed on the requirements of the Commodities Exchange Act without the necessity of legal interpretation by the Court (if the *Zieg* Court even considered the *Owens* rationale) seems rash. Sometimes, though perhaps rarely, a complaint alleging negligence by violation of a federal statute shows that legal construction and interpretation of such a federal statute will be necessary. As noted above, Respondents' complaints pose such necessity.

G. The alleged federal law violations are not tangential or potential issues but will assume prominence in the trial of Respondents' claims

1. Though they minimized such claims in seeking remand, Respondents did seek a private recovery for Food, Drug and Cosmetic Act violations.

Both courts below focused on the "presumption of negligence" allegation of Respondents' Fourth Cause of Action, assuming that this was the only nexus between the claimed federal violation and Respondents' claims. However, if the "presumption" paragraph be stricken, a different picture emerges. The Fourth Cause of Action still alleges injuries proximately caused by the claimed violations, i.e., *a private cause of action*. Likewise, the Fifth Cause of Action alleges, *inter alia*, injuries proximately caused by Petitioner's failure "to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law." J.A. 24, 33. This alleged misdeed is distinct from the

"misbranding" alleged in the previous cause of action. These claims have not been disposed of by either court. By contrast, the district court in *Griffin* v. *O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717 (S.D. Ohio 1985), the *subsequent* local decision which ruled private Food, Drug and Cosmetic Act claims unavailable, ordered the Food, Drug and Cosmetic Act claim in that case stricken from the complaint. *Id.* at 720.

Respondents' private claims under the Food, Drug and Cosmetic Act, are (as they now concede) legally insufficient, but not insubstantial in a jurisdictional sense. No decision of this Court forecloses them. The possibility that they might fail to state a claim upon which relief can be granted is not a jurisdictional impediment unless they are "clearly . . . immaterial and made solely for the purpose of obtaining jurisdiction." *Mt. Healthy City Board of Education* v. *Doyle*, 429 U.S. 273, 278 (1976). If they fail to state a claim upon which relief can be granted, they must be dismissed *on their merits*. In *Bell* v. *Hood*, 327 U.S. 678 (1946), this Court stated:

> Jurisdiction, therefore, is not defeated as respondents seem to contend, by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. For it is well settled that the failure to state a proper cause of action calls for a judgment on the merits and not for a dismissal for want of jurisdiction. Whether the complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact it must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits not for want of jurisdiction. *Swafford* v. *Templeton*, 185 U.S. 487, 493, 494; *Binderup* v. *Pathe Exchange*, 263 U.S. 291, 305-308.

Id. at 682.

Respondents' self-serving impeachment of their federal claims (though without withdrawing them) in seeking remand, does not change the jurisdictional fact that they were pled.

No judgment prevents Respondents from pressing their private Food, Drug and Cosmetic Act claims in state court if these actions are remanded. The District Court had jurisdiction to strike such claims, as it did in *Griffin*, but bypassed the necessity of doing so by its *forum non conveniens* dismissal. While such claims remain unstricken, the jurisdiction which they confer likewise remains.

2. Respondents will rely upon the alleged Food, Drug and Cosmetic Act violations to prove negligence *per se* and that Bendectin was a "defective product."

In arguing for remand, Respondents stated that their claims on the alleged Food, Drug and Cosmetic Act violations constituted negligence *per se*, i.e., negligence as a matter of law, under Ohio law. Such a legal contention, if adopted, would remove any issue of due care from the Fourth Cause of Action, further explaining why it was separately pled. Respondents also asserted that the claimed federal violations were probative on the question whether Bendectin was a "defective product," a central issue of their *Second* and *Third* Cause of Action. J.A. 19-21, 29-30.

For the foregoing reasons, the claimed federal law violations are not "lurking in the background" of Respondents' suits, but will have a major importance in the trial of their claims.

II. WHERE A CLAIM WHICH "NECESSARILY DEPENDS" ON RESOLUTION OF AN ISSUE OF FEDERAL LAW IS JOINED WITH OTHER CLAIMS NOT BASED ON FEDERAL LAW WHICH WOULD, IF PLAINTIFF PREVAILS, OBVIATE THE FEDERAL QUESTION, THE PENDENCY OF SUCH LOCAL CLAIMS DOES NOT DEPRIVE THE DISTRICT COURT OF JURISDICTION.

A. The District Court correctly ruled that the essential federal question of Respondents' Fourth Cause of Action conferred jurisdiction, notwithstanding the fact that Respondents might alternatively recover on their other, non-federal claims.

Respondents' complaints show that they also claim rights of recovery wholly apart from the violations of federal law which they allege in their Fourth Cause of Action. The District Court made no mention of this undisputed fact, focusing on the essential element of the Fourth Cause of Action. The relationship of the Fourth Cause of Action to the rest of the complaint and, in particular, to the First Cause of Action, prompted the Court of Appeals to reverse the District Court, concluding that subject matter jurisdiction was lacking. Accordingly, an appreciation of the complaint and the interrelationship of its various parts is necessary.

Respondents allege that the drug Bendectin caused their childrens' birth defects. The alleged bases for liability are several. The First Cause of Action asserts the negligence of the Petitioner "in developing, marketing, producing, manufacturing, distributing and selling" Bendectin and "in failing to test or inadequately testing the potential birth defect producing effects" of Bendectin and "in failing to warn the users of Bendectin of the potential birth defect producing effects. . . ." J.A. 1 19, 28. Respondents' proof of their First Cause of Action would require their demonstration of the applicable standard of care and a breach of that standard. This

would be a formidable and complex task, requiring that Respondents show how a reasonable maker or seller of prescription drugs conducts its business.

Respondents' pled their Fourth Cause of Action separately because it alleges a separate legal basis for assigning fault, i.e., federal violations. Respondents' do not say what law they rely upon for their contention that the asserted violations "constitute a rebuttable presumption of negligence." However, this allegation means that the Respondents' *prima facie* case will be demonstrated by showing that such violation occurred and by producing some evidence that it caused their injuries. They may dispense with proving the standard of care for a reasonable drug manufacturer or proving that the Petitioner violated that standard. Their concession that the presumption is "rebuttable" would seemingly allow Petitioner to demonstrate that it exercised due care, whether or not it had committed a violation of law. However, the burden of going forward with proof concerning due care would be shifted from the plaintiff to the defendant.

The Respondents' Fourth Cause of Action is distinct from their First because the culpable act which they undertake to prove is different. This is why their First Cause of Action alleges that the defendant's "negligence" caused the Respondents' injuries, J.A. 19, 29, ¶¶ 9, 10, while their Fourth Cause of Action, asserts that "defendant's violation of said federal statutes" caused such injuries. J.A. 22, 32, ¶ 27. Respondents' Fourth Cause of Action is premised, not on the quality of Petitioner's acts or omissions as *negligent*, but on their character as unlawful *as a federal matter*. Their complaint "establishes . . . that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Franchise Tax Board*, 463 U.S. at 27-28.

The Court of Appeals did not dispute (or even address) the fact that the Fourth Cause of Action was dependent on this federal issue. Rather, it found that Respondents might prove "negligence" without proof of the federal violation and that

the federal violation was thus not "necessary" to Respondents' "right to relief." J.A. 10. The Court of Appeals obviously read the Fourth Cause of Action in combination with the First and treated these two counts as asserting a single "cause of action" and a single "right to relief" for negligence. *Id.* The Court of Appeals erred by applying a concept of "cause of action" and "right to relief" which was broader than that which this Court has traditionally employed in determining whether federal question jurisdiction is present. If *any* "cause of action" or *any* "right to relief" requires construction and interpretation of federal law, jurisdiction is present.

B. The question whether a right to relief asserted in a "cause of action" is federally created or involves an essential federal issue is answered by consideration of the cause of action itself, regardless of plaintiffs' potential for recovery on non-federal grounds.

If a plaintiff alleges a cause of action which relies on a proposition of federal law, it is irrelevant that plaintiff might achieve a recovery based on other claims which do not depend on that federal issue. This is illustrated by this Court's analysis of the complaint in *Franchise Tax Board*. That complaint consisted of two "causes of action." The first sought recovery on three tax levies issued pursuant to the California Tax Code. The second sought a declaration that the defendants were "legally obligated to honor future levies by the Board," asserting that the defendant's refusals to honor the levies were premised on the preemptive effect of The Employers Retirement Income Security Act (ERISA). 463 U.S. at 7.

This Court dealt only briefly with the first cause of action, observing that the issue of preemption by ERISA was purely defensive and that the Tax Board's cause of action itself arose solely under state law. 463 U.S. at 13. The Court then ruled out "federal question" jurisdiction under the second cause of

action, holding that resort to a declaratory judgment as a form of action could not convert an implicitly defensive issue into a necessary element of the plaintiff's affirmative case. 463 U.S. at 18-19.

The facts in *Franchise Tax Board* were susceptible to the same analysis as that which the Court of Appeals applied to the Respondents' claims. Indeed, such would have provided a more direct basis upon which to resolve the case than that which the Court employed. In *Franchise Tax Board*, this Court noted:

> Appellant's complaint sets forth two "causes of action," one of which expressly refers to ERISA; *if either comes within the original jurisdiction of the federal courts, removal was proper as to the whole case*. See 28 U.S.C. § 1441(c).

463 U.S. at 13.

This pronouncement concerned two causes of action which were, in their legal theory, *duplicative*. Had the Tax Board prevailed on its first cause of action for recovery on the three tax levies, such would have mooted the second cause of action. The issue of preemption of the state tax code by ERISA would necessarily have been decided under the first cause of action, but only as an affirmative defense raised by the trustees. The first cause of action would have determined the plaintiff's *entire right to relief*. This fact was not even discussed by this Court. The "causes of action" were evaluated *separately* and regardless of the fact that the first and clearly *nonfederal* claim was sufficient to decide the whole controversy.

A similar jurisdictional evaluation was conducted by the circuit court in *Westmoreland Hospital Assoc.* v. *Blue Cross*, 605 F.2d 119 (3rd Cir. 1979), *cert. denied*, 444 U.S. 1077 (1980). In *Westmoreland*, several hospitals sued a health insurer in state court. The hospitals alleged breach of a contract to reimburse the hospitals for care of subscriber patients on a

complicated "cost" basis rather than at the hospitals' standard rates. The plaintiffs claimed that Blue Cross had wrongly withheld a part of the reimbursement, in that it routinely deducted from the reimbursements certain grant payments received by them under the Community Mental Health Centers Act (42 U.S.C. § 2688 *et. seq.*). The hospitals contended that this practice violated a provision against such grants' being applied to cross-subsidize payments by insurers. *Id.* at 121-22. Defendant removed this suit to federal court.

The hospitals moved for remand, but their motion was denied. The action was tried and decided adversely to the hospitals, and, as the circuit court reports, solely on state law grounds. The hospitals again attacked jurisdiction on appeal, urging that their allegations of federal violation were not, on the face of their complaint, indispensable to their recovery. The Third Circuit held that this fact was inconsequential as to jurisdiction.

> There is much force to appellants' contention that their claim for relief involved only the interpretation of the Blue Cross contract under Pennsylvania law. Certainly, this was the theory on which the law suit was ultimetely decided. But our inquiry as to the presence of federal jurisdiction is not on the basis of how a complaint *could* have been structured or of what theory was eventually relied upon at trial. [Emphasis in original].
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> Notwithstanding their contention that it would have been possible to decide the contract dispute solely on state law precepts, we see that appellants gratuitously volunteered on the face of their complaint legal conclusions based on federal statutes and regulations. Although these allegations may have been unnecessary for the ultimate disposition of the case, and here we are accepting the appellants' premise, surplusage of federal claims in pleadings is not the test.
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> * * *

> To accept their contention would require us to evaluate the question of federal jurisdiction at the time of trial in the federal court and to decide that subject matter jurisdiction did not obtain because appellants went to trial on state law theories only. To do so would be to ignore the rule in removal cases that subject matter jurisdiction is to be determined from the face of the complaint and on the basis of the record in the state court, *at the time* the petition for removal is presented. [Emphasis in original]. The hospitals' complaint, so viewed, *reveals alternative bases for relief against Blue Cross, namely, that the hospitals were entitled to relief under the contract whether it was interpreted according to state law principles or under the federal mental health statutes.* Because appellants' complaint was based in part on federal statutes, and federal agency regulations and interpretations, we conclude that there was jurisdiction under 28 U.S.C. § 1331(a).

605 F.2d at 123-124 (emphasis added).

No plaintiff is ever bound to pursue a federal contention relied upon in his complaint. Liberal amendments to pleadings are the rule in federal court, Fed. R. Civ. P. 15, and the trial court must grant appropriate relief even if it is not requested in the complaint. Fed. R. Civ. P. 54(c). Still, complaints are evaluated for subject matter jurisdiction based on the assumption that the plaintiff intends to try all the "causes of action" which he pleads. Rule 8(e)(2) of the Federal Rules of Civil Procedure provides: "When two or more statements [of a claim] are made in the alternative and one of them, if made independently would be sufficient, the pleading is not made insufficient by the insufficiency of one or more of the alternative statements." The same rule must apply to the jurisdictional sufficiency of a claim upon which federal question jurisdiction depends. In holding, in *Franchise Tax Board*, that jurisdiction is present where a plaintiff's "right to relief" necessarily depends on a federal question, this Court

did not require that the plaintiff seek relief *solely* on federal grounds, or that *all* his "causes of action" be based on federal law.

The phrase "cause of action" has meant different things in different situations. *United Mine Workers* v. *Gibbs*, 383 U.S. 715, 722-724 (1966). In discussing the plaintiff's "causes of action" in *Franchise Tax Board*, this Court used such term in a narrower sense than that applied in other contexts. In more traditional parlance, the doctrine of *res judicata* is also known as the rule against splitting a "cause of action." This was the sense in which this Court used the term in *Baltimore S.S. Co.* v. *Phillips*, 274 U.S. 316 (1927), ruling that a seaman who had brought and lost a suit for negligence could not begin a new suit against the same defendant. He was precluded from a new suit on the same "cause of action", though the facts he alleged might be different. *Id.* at 321.

In *Hurn* v. *Oursler*, 289 U.S. 238 (1933), this Court defined the limits of pendent jurisdiction in terms of the power of a federal court to decide an entire "cause of action," again meaning all the legal bases for recovery for a single wrong, including those based on state *and* federal law. Against that analytical framework, a "cause of action" was subject to federal jurisdiction if *any* of the theories of recovery necessitated a decision on a substantial federal question. This was clearly not the sense in which this Court used "cause of action" in analyzing the *Franchise Tax Board* complaint.

Respondents' "cause of action," *in the sense of their general right to recover for the injuries which they assert*, does *not* "necessarily depend" on a disputed question of federal law. They could, theoretically, prove negligence without resort to the presumption of negligence based upon the alleged Food, Drug and Cosmetic Act violations. Likewise, they might prove a case for strict liability in tort or breach of express or implied warranties without introducing proof of the alleged violations. However, this is not the test of federal jurisdiction under 28 U.S.C. § 1331, even as to *federally created* "causes of action."

The Sixth Circuit relied upon *Franchise Tax Board* for the proposition that federal question jurisdiction would lie where "a well-pleaded complaint establishes . . . that federal law creates the cause of action . . . ." J.A. 9. To say that federal law "creates the cause of action" does not require a finding that the plaintiff would have no lawsuit but for the federal statute upon which he sues. A plaintiff invoking federal question jurisdiction often joins in his complaint state and federal claims each of which seek the same relief for the same actionable wrong. For example, in *United Mine Workers* v. *Gibbs*, 383 U.S. 715 (1966), the plaintiff premised federal jurisdiction on an allegation of a secondary boycott under section 303 of the Labor Management Relations Act and on the common law of Tennessee.

Measured by the definition of "cause of action" in *Baltimore SS Co.* v. *Phillips* and *Hurn* v. *Oursler*, Gibbs' complaint did not show that federal law "created" his "cause of action." Gibbs' *overall* "right to relief" did not "necessarily depend" on his federal labor law claim. In fact, the federal claim upon which Gibbs invoked jurisdiction was eventually found to be legally insufficient. Tennessee state law supplied the *only* right to recovery.

As illustrated in *Gibbs*, to say that federal law "creates the cause of action" does not imply that a plaintiff must have no "right to relief" apart from that granted by the federal statute. A plaintiff may often have more than one "right to relief," and more than "one cause of action" in that he has one or more state *and* federal grounds for his claim. The same concept of "cause of action" and "right to relief" applies to the alternate basis for federal jurisdiction as noted in *Franchise Tax Board*.

The Court of Appeals read *Franchise Tax Board* to preclude federal jurisdiction because the Respondents' complaint included *another* "cause of action" for negligence, one without reference to federal law. The Court of Appeals was apparently untroubled by the fact that the Respondents

might also recover on strict liability or breach of warranty without any reference to negligence. It saw the First and Fourth Causes of Action in the Respondents' complaints as alleging a single "right to relief." This was based upon the use of the word "negligence" in each such claim. While the Respondents' First and Fourth Causes of Action each include the word "negligence," the differences between these two claims outweigh their similarities.

The Respondents contend that violation of a *specific* safety statute resulting in injury to a member of the class which the statute is designed to protect constitutes negligence *per se*, i.e., negligence as a matter of law, in Ohio. By this standard, such a violation is more than grounds for a presumption of negligence but constitutes a civil wrong in itself to which Petitioner's proof of due care would be deemed irrelevant. If this view of Ohio law were applied,[10] the separate and distinct character of the Fourth Cause of Action is all the more apparent. Respondents' Fourth Cause of Action asserts a separate and distinct "right to relief" which necessarily depends on their proof of a violation of the Food, Drug and Cosmetic Act. The District Court correctly found jurisdiction on this basis.

As a member of the pharmaceutical industry, Merrell Dow Pharmaceuticals Inc. is governed by the Food, Drug and Cosmetic Act and the comprehensive regulations promulgated thereunder as administered by the Food and Drug Administration. The appropriate analysis of Respondents' claims that Petitioner violated this regulatory scheme thus requires construction and interpretation of federal statutes and administrative regulations. This is in sharp contrast to most negligence complaints which, although they may allege violations of statutes, do not actually require the construction and interpretation of federal statutes.

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10 Petitioner has and does dispute that Ohio law would ever apply in these actions. J.A. 50.

The Respondents were not obliged to rely upon federal law in their complaints. Had they refrained from doing so, or had they renounced that reliance when seeking remand, their cases would not now be before this Court. The risk that plaintiffs will contrive federal jurisdiction by far-fetched allegations is not a new problem but one with which the district courts routinely and effectively deal. Petitioner cannot be accused of contriving removal jurisdiction in the instant cases, since it offered to accept remand if Respondents would abandon the novel federal propositions upon which their Fourth Causes of Action were based. J.A. 52-54. Having cloaked the extraterritorial element of their accusations of "misbranding" in inaccurate factual allegations (after first alleging that Petitioner violated the Food, Drug and Cosmetic Act as it applies to drugs manufactured and sold in the U.S.), the Respondents would not desist, even to achieve remand.

It is not the office of the federal courts to oversee the routine application of settled federal law to state-created claims. Here the direct enforcement of the involved complex regulatory statute has been delegated by Congress solely to an administrative agency with the appropriate special expertise. 21 U.S.C. § 337. Moreover, the Respondents seek to break new ground by "exporting" federal law to other countries and "importing" foreign tort claims for trial in state court, based on the extraterritorial operation of such federal law.

Under the Respondents' view of federal jurisdiction, involved state courts may determine individually, in each case before them, whether Petitioner violated the Food, Drug and Cosmetic Act as to Bendectin, Debendox or Canadian Bendectin. Each such case may progress at its own pace through each state's court system with the only avenue for imposing uniformity of federal interpretation being the jurisdiction, on *certiorari*, of this Court. Such cases will require not only the application but the development of federal law in a context for which the statute (as Respondents vigorously point out) was not designed, i.e., private enforcement.

As this case dramatically illustrates, because of the federal precedents on *forum non conveniens*, the state forum will be most attractive to foreign plaintiffs whose claim as intended beneficiaries of the statute is most tenuous. Decisions which sustain such foreign plaintiffs' credentials as members of the "protected class" will only enhance the attractiveness of an American forum to such foreign citizens. In such a situation, the federal question of a foreign citizen's complaint is one of great significance.

The complaints of the Respondents pose substantial federal questions upon which their Fourth Causes of Action are unavoidably dependent. Their cases arise under federal law and this Court is respectfully urged to so rule.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be reversed and the judgment of the District Court reinstated by this Court without modification.

Respectfully submitted,

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